REMARKS

Claims 301, 303, 304, 307-310, and 322-333 are pending in the application.

Improper Final Rejection

As argued in Applicant's Request for reconsideration: By the Office's November 20, 2003 Action, the matter was placed under final rejection. Applicant disagrees. Specifically, the Office cited United States Patent Number 5,840,358 issued to Hofler, et al., in its rejection of Claims 301, 303-310 (presumed to be Claims 303, 304, 307-310) under 35 U.S.C. §§102(b) or 103(a) in the alternative. The Office's action of November 20, 2003 was the first citation of the Dee's reference. As the Manual of Patent Examining Procedure notes:

> Under present practice, second or any subsequent actions on the merits shall be final, *except* where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). ...Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will *not be made final if it includes a rejection, on newly cited art*, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art. *M.P.E.P. §706.07(a).* Emphasis added.

Thus, not only is the finality of the rejection improper, but the citation of this reference at this late date may indicate Applicant is facing a piecemeal examination which is discouraged in *M.P.E.P. §707.07(g).*

Claim Rejection 35 U.S.C. § 102

As best understood by the Applicant, Claims 301, 303, 304, 307-310 stand rejected either as anticipated under 35 U.S.C. §102(b), or as obvious under 35 U.S.C. §103(a) over Forber et al., (sic) Forberg et al., (DD 138273) hereinafter Forberg et al. Applicant respectfully

disagrees. References in this Reply refer to the translated summary provided of the Forberg et al. reference.

Claims 301, 303, 304, 307-310 have been rejected under 35 U.S.C. §102(b) as anticipated by Forberg et al. Applicant traverses. Anticipation cannot be established when "the prior art is lacking or missing a specific feature or the structure of the claimed invention." *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). This is the present case. The presently claimed method as recited in Claim 301 discloses a method for combating microbial infections in animals. Claim 301 further recites the steps of ". . .reducing said fermentation broth to obtain fermentation solids **consisting essentially of** said antibiotic; drying said fermentation solids to produce a dry solid; and granulating said dry solid to produce granulated fermentation solids comprising **uncompacted** granules having a substantially uniform particle size, wherein the granules have an antimicrobial concentration sufficient to treat an animal of at least 10 g/lb." First, Forberg fails to teach a method of combating microbial infection which includes obtaining fermentation solids consisting essentially of antibiotic generated from a fermentation medium. Forberg instead teaches a medicinal fodder wherein a pure base, salt, or derivative thereof is utilized to obtain the desired activity. Forberg, Page 4 last paragraph. This is not the present invention where the material is formed essentially of fermentation solids obtained from a fermentation broth.

Moreover, the Forberg reference reinforces Applicant's position by noting "The economically feasible manufacturing of an effective premix by adding a waste product or secondary material of the fermentation is not known." Forberg, Page 4, first paragraph. Thus, not only does Forberg fail to teach a method of combating microbial infection in

animals, but the Forberg reference also indicates the recited method is "not known". If, the recited method were known then Forberg would know both the economic and procedural feasibility of the process. As the Office is aware, "When more than one reference is required to establish unpatentability anticipation under § 102 cannot be found, and validity is determined in terms of obviousness under § 103." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 20 USPQ 2d 1746, 1748 (Fed. Cir. 1991). Therefore, the pending rejection under 35 U.S.C. §102(b) is improper because Forberg fails to teach a method including the utilization of fermentation solids consisting essentially of antibiotic obtained from a fermentation broth.

Further, the invention in controversy recites a method for preparing a medicated supplement with the source of antibiotic being from an organism in the fermentation medium and in the form of **uncompacted** granules with substantially uniform particle size. As best understood by the Applicant, the Office (appears) to argue that the fluidized bed process results in uncompacted granules with uniform particle distribution. This is incorrect. The Office (apparently) is attempting to introduce the Hofler et al. reference (United States Patent Number 5,840,358) to indicate that, inherently, fluidized bed processes result in uncompacted granules with a uniform particle distribution. As the Office is aware, "[i]nherency. . .may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578,581, 212 USPQ 323, 326 (C.C.P.A. 1981) *citing Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (C.C.P.A. 1939). Emphasis added. The instant Action states "Ar to fluidized-beds; we do not in PTO, have testing capabilities, but examiner understands the fluidized bed to operate with uniformly sized no 226 apertures, and thus one would expect uniform sized particles. If this is not so, applicant should so show." Instant Action, page 2 paragraph 3. Applicant respectfully disagrees.

First, this is the first time the Hofler reference has been cited, thus Applicant respectfully submits that the finality of the pending rejection is improper, as argued previously. Further, the Office is incorrect because Hofler clearly indicates that fluidized-bed process requires compaction and thus doesn't meet the limitation of "**uncompacted** granules with substantially uniform particle size". For example, Hofler teaches,". . .wherein the supplement contains wholly or predominantly a fermentation broth, which is characterised in that the fermentation broth is granulated, compacted and dried in a fluidised bed. . ." Hofler, Abstract. Further the reference Hofler states, "Due to the fact that the fermentation broth is granulated, compacted and dried in a fluidised bed. . .", Hofler, Col. 3, lines 20-21. Both of these cited portions of the Hofler reference indicate that fluidized bed processes require the material be compacted, therefore the Hofler reference indicates that Forberg could not possibly teach the method including fermentation solid which are "**uncompacted** granules with substantially uniform particle size" as asserted by the Office.

In contrast, if the Office is attempting to reject the Instant Application under 35 U.S.C. 103(a) over Forberg in view of Hofler, the finality of the pending rejection is improper because this is the first introduction of the Hofler reference. Further, when applying 35 U.S.C. §103, the following tenets of patent law must be adhered to: (A) the claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141 and Hodosh v. Block Drug Co., Inc.,* 786 F.2d 1136, 1143 n.5, 220 USPQ 182, 187 n.5 (Fed. Cir. 1986). In the present case, even if one were to combine the Forberg reference with the Hofler reference, one would be informed that it is necessary in a fluidized bed process to compress the

granules. Therefore, even if one of ordinary skill in the art were motivated to combine Forberg with Holfer the resultant combination fails to result in the pending invention, as a fluidized bed process (as described in Holfer) requires compaction and therefore does not meet the limitation of **uncompacted** granules.

Additionally, as the Office is well aware "In proceeding before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art..." *In re Fritch*, 972 F.2d 1260, 24 USPQ.2d 1780, 1783 (Fed. Cir. 1992). Therefore, the burden is on the Office to show that the fluidized bed process results in "**uncompacted** granules with substantially uniform particle size" rather than on the Applicant, as indicated by the Examiner's statement that, "If this is not so, applicant should so show." Removal of the pending rejections is respectfully requested.

For at least the foregoing reasons, Applicant respectfully requests that the pending rejections under 35 U.S.C. §102(b) or in the alternative 35 U.S.C. §103(a) be removed and Claims 301, 303, 304, and 307-310 allowed.

As the Office has not forwarded any additional arguments with respect to Claims 322-333 under either 35 U.S.C. §§102(b) or 103(a), Applicant respectfully resubmits the Arguments forwarded in the September 5, 2003 Response and in the March 21, 2003 arguments and generally as argued above. Applicant will not burden the record further. Allowance of Claims 322-333 is earnestly solicited.

CONCLUSION

In light of the forgoing, reconsideration and allowance of the claims is earnestly solicited.

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